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## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Application No. Applicant(s) 10/562 443 THOREL, JEAN-NOEL Office Action Summary Examiner Art Unit Jennifer A. Berrios 1619 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 05 March 2010. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 8-11 and 14-25 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 8-11 and 14-25 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage

application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Jennifer A. Berríos in Art Unit 1619.

This office action is in response to the reply filed 3/5/2010, wherein claim 8 has been amended and claims 1-7 and claims 12-13 have been cancelled.

Currently claims 8-11 and 14-25 are being examined.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### Response to Arguments

Applicant argues that claim 8 recites, inter alia, "a method for decreasing comedogenesis in skin suffering from acne by preventing thickening of sebum due to oxidation brought about by bacterial components and UV radiation." The applied references fail to teach, suggest, or establish any reason or rationale to provide such features. Briganti merely discloses ROS produced by neutrophils may be responsible for oxidation of sebum and that degradation of squalene oxidation products in the surface of the skin causes the formation of comedos. Thus, Briganti does not cure the deficiencies of Pykett because it fails to establish any reason or rationale to prevent

Art Unit: 1619

thickening of sebum "due to oxidation brought about by bacterial components and UV radiation," Schiltz discloses dodecyl gallate for its antioxidant properties for achieving skin anti-aging benefits and is only applied for its alleged teachings of the features of dependent claim 10, and thus does not cure the deficiencies of Pykett, Briganti and Wall with respect to claim 8.

This is not persuasive. Applicant argues that the composition of the prior art does not recite or suggest Applicant's combination of ingredients for the same purpose or for utilizing the same operative mechanisms. The composition of the prior art need not claim the same purpose and mechanism as that of the instant claims. As the composition claimed and that of the prior art are the same and the active method steps are taught, they are expected to have the same properties, absent any evidence to the contrary.

MPEP 2112 I. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

#### Maintained Rejections

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-9, 11, and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,195,787 (2007, Pykett et al) in view of "Antioxidant activity, lipid peroxidation and skin diseases. What's new," (2003, Briganti et al) and evidenced by "Antioxidants in Prevention of Reperfusion Damage of Vascular Endothelium" (2000, Wall).

The instant claims recite a method for treating acne, the method comprising applying to skin a dermatological and/or cosmetic composition comprising at least one lipophilic antioxidant selected from the group consisting of gallates, flavonoids extracted from gingko biloba, and butylated hydroxytoluene (BHT). The composition further comprises a hydrophilic antioxidant selected from mannitol and vitamin C. The total amount of antioxidant in the composition is from 0.0001 to 20% wt of the composition.

Pykett teaches topical cosmetic compositions for application to the skin to protect against oxidative damage (sunlight, etc.) related to aging, comprising a synergistic mixture of anti-free-radical agents selected from compound such as ascorbic acid

Art Unit: 1619

(hydrophilic antioxidant) and herbal extracts from gingko biloba (lipophilic antioxidant), inter alia [abstract]. claims 8, 9, and 11 Antioxidant activity from gingko biloba is believed to be from flavonglycocides [col 2, line 37]. One embodiment includes mannitol (hydrophilic antioxidant) and BHT (butylated hydroxytoluene and lipophilic antioxidant) [col 16, Example 13]. claims 8, 9, and 11 The total amount of antioxidants in the composition ranges from 0.05 to 10% [col 2, line 56]. claims 14-25 The compositions were applied to the skin of the forearm [col 28, lines 58-59]. Pykett does not teach treatment of acne.

Briganti teaches a correlation between oxidative stress and skin disease such as acne [pg 664, col 2]. Briganti suggests antioxidant supplementation could be a therapeutic approach to atopic dermatitis [pg 664, col 2]. In comedo lesions, reactive oxidative species (ROS) overflows due to a lack of inhibitors. Topical application of antioxidants can be effective in improving the efficacy or preventing deleterious effects of therapeutics for acne [pg 666, col 1].

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Pykett and Briganti. One of ordinary skill in the art at the time of the invention would have been motivated to use antioxidants such as BHT and gingko extract to treat skin diseases and acne as Briganti teaches use of antioxidants for treatment of dermatitis and acne. One of skill in the art would have a reasonable expectation of success as both Pykett and Briganti teaches topical composition for application to the skin, which comprise antioxidants.

While Pykett does not teach use of mannitol as an antioxidant, this property was known in the art as evidenced by Wall [pg 69, col 1].

Art Unit: 1619

Regarding claim 1: Claim 1 recited "a method for decreasing comedogenesis in skin ... by preventing thickening of the sebum due to oxidation brought by bacterial components and UV radiation." It is noted that this phrase is a recitation of functional properties of composition claims and carries no patentable weight. As the composition taught by Pykett and Briganti teach all the structural limitations of the instant claims (a composition comprising at least one lipophilic antioxidant, which is applied to skin for the treatment of acne), it's expected that the composition of the prior art and the composition instantly claims would have the same properties, absent evidence to the contrary.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Pykett in view Briganti and evidenced by Wall as applied to claims 8-9, 11, and 1425 above, and further in view of U.S. Pre-grant Application Publication

2003/0095940 (Schiltz).

The instant claims are as recited above. The claims further require dodecyl gallate as a lipophilic antioxidant.

The combined teachings of Pykett, Briganti, and Wall are relied upon above.

None of the references teach dodecyl gallate.

Schiltz teaches anti-ageing compositions that can include antioxidants such as dodecyl gallate [pg 4, par 27]. claim 10

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Pykett/Briganti and Schiltz.

One of ordinary skill in the art at the time of the invention would have been motivated to

Art Unit: 1619

add dodecyl gallate to the composition of Pykett with a reasonable expectation of success as the Pykett teaches a mixture of antioxidants.

Therefore the invention as a whole would have been prima facie obvious at the time it was made.

### New Rejections

#### Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 8, 14, 18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Sebaq et al (US 5,411,742).

Sebag teaches compositions for the treatment of acne. Example 5 demonstrates a skin care cream that comprises butylated hydroxytoluene (lipophilic antioxidant). Sebag teaches that after application of the cream in the evening and in the moming, the face of the subject having skin with acne, experiences a sharp regression of acne. Example 5 demonstrates that use of 0.042% of BHT.

Regarding claim 1: Claim 1 recited "a method for decreasing comedogenesis in skin ... by preventing thickening of the sebum due to oxidation brought by bacterial components and UV radiation." It is noted that this phrase is a recitation of functional properties of composition claims and carries no patentable weight. As the composition taught by Sebag teaches all the structural limitations of the instant claims (a

Art Unit: 1619

composition comprising at least one lipophilic antioxidant, which is applied to skin for the treatment of acne), it's expected that the composition of the prior art and the composition instantly claims would have the same properties, absent evidence to the contrary.

 Claims 8, 14, 18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Marvel (US 6,531,141).

Marvel teaches an oil-in-water emulsion containing tretinoin and the use thereof in mitigating skin disorders, such as acne, etc (Abs). The oil in water emulsion comprises 0.001% to about 1% by weight of an antioxidant (eg. BHT, tocopherol and ascorbic acid) (Col. 2. lines 15-17).

Claim 3 demonstrates an oil-in-water emulsion having 0.001 to about 1% of BHT.

Claim 16 demonstrates an O/W emulsion having BHT which is administered to the skin of a human for mitigating a skin condition, such as acne.

Regarding claim 1: Claim 1 recited "a method for decreasing comedogenesis in skin ... by preventing thickening of the sebum due to oxidation brought by bacterial components and UV radiation." It is noted that this phrase is a recitation of functional properties of composition claims and carries no patentable weight. As the composition taught by Sebag teaches all the structural limitations of the instant claims (a composition comprising at least one lipophilic antioxidant, which is applied to skin for the treatment of acne), it's expected that the composition of the prior art and the composition instantly claims would have the same properties, absent evidence to the contrary.

#### Claim Rejections - 35 USC § 103

 Claims 8-10, 11 and 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marvel (US 6,531,141), as applied to claims 8, 14, 18 and 22 above.

Marvel teaches all the limitations of claims 8, 14, 18 and 22 above, but fails to teach the composition to comprise a combination of BHT and a hydrophilic antioxidant.

Marvel teaches that suitable antioxidants include BHT, tocopherol and ascorbic acid. One of skill in the art would have recognized BHT and ascorbic acid to be functional equivalents, as Marvel teaches that both are suitable for use in O/W emulsion for topical application to the skin for the treatment of acne. As such, it would have been prima facie obvious for one of skill in the art to combine both BHT and ascorbic acid in order to create a third composition, with a reasonable expectation of success.

MPEP 2144.06 recites "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)."

Regarding claims 14-25: Claim 2 teaches that anti-oxidants are present in amounts ranging from 0.001% to about 1%, which overlap with the instantly claimed ranges.

#### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berrios whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 270-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Berríos/ Examiner, Art Unit 1619

> /Tracy Vivlemore/ Primary Examiner, Art Unit 1635